K021761 p1/1

SEP 17 2002

PREMIER™ Anterior Cervical Plate System
510(k) Summary
May 2002

I. **Company:**

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** PREMIER™ Anterior Cervical Plate System

Classification Name: Spinal intervertebral body fixation orthosis

III. **Device Description:**

The PREMIER™ Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The PREMIER™ Anterior Cervical Plate System features a sliding washer that covers the heads of the bone screws to prevent screw back-out. The sliding washer is fixed into place with a set screw. The sliding washer and set screw come pre-assembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The PREMIER™ Anterior Cervical Plate System implant components are made from titanium alloy such as described by ASTM F136 or ISO 5832-3. This material is not compatible with other metal alloys. Do not use any of the PREMIER™ Anterior Cervical Plate System components with the components from any other system or manufacturer. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

IV. **Device Indications**:

Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

V. **Substantial Equivalence**:

The PREMIER™ Anterior Cervical Plate System was claimed to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

Richard W. Treharne, Ph.D.
Senior Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K021761
Trade/Device Name: PREMIER™ Anterior Cervical Plate System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 21, 2002
Received: August 23, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021761

Device Name: PREMIER™ Anterior Cervical Plate System

Indications for Use:

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Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ___ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Milhaum
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021761

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